



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M 24377

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED

March 3, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 18

Maurice R. Taylor II
Chairman of the Board and CEO
Chronimed, Inc.
10900 Red Circle Drive
Minnetonka, Minnesota 55343

Dear Mr. Taylor:

We are writing to you because on December 2-22, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the glucose test strips and meters that are manufactured by your facility at 6214 Bury Drive, Eden Prairie, MN.

Under a United States Federal law, the Federal Food, Drug and Cosmetic Act (Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. They are medical devices as defined by Section 201(h) of the Act.



Our inspection found that the devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, facilities or controls used for manufacturing, packing, storage, or installation of the medical devices are not in conformance with the Good Manufacturing Practices (GMP) requirements set forth in the Quality System Regulations for Medical Devices as prescribed by Title 21, Code of Federal Regulations, (CFR), Part 820.

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Our inspection found your products are in violation of the law because of:

1. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints (21 CFR 820.198). For example:
 - a. Device quality issues reported by customers to the Technical Service Group have not been reviewed and evaluated to determine if investigations are necessary.
 - b. Complaint files are not maintained, complaint handling procedures are not followed, and records of complaint investigations are incomplete.
2. Failure to establish and maintain procedures for acceptance activities (21 CFR 820.80) in that your firm has not followed its own Quality System Release procedure for glucose test strips. The procedure does not allow re-testing of failed strips nor does it specify that the strips must fail testing twice in order to be rejected. You re-tested and released three batches of glucose test strips. Additionally, glucose strips (lot 2458C) were used in production despite the lack of a control test on 

3. Failure to establish and maintain procedures for implementing corrective and preventive action (21 CFR 820.100) in that all sources of quality data are not analyzed to identify existing and potential causes of nonconforming product and your firm has not documented the evaluation of glucose strips that have been discarded (lots 2528A and 2468A) and the retest of glucose test strips.
4. Failure to establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics (21 CFR 820.250) in that your firm has not demonstrated the acceptability of the statistical techniques used in the validation and routine inspection of the glucose strips.

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5. Failure to establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation as required by 21 CFR 820.30(b). For example, there is no plan for the software validation for Version 104.
6. Failure to ensure that the design input requirements are appropriate to assure that the device will perform to meet its intended use and the needs of the user as required by 21 CFR 820.30(c). For example, there is no documentation identifying the final, desired specifications (inputs) required for the Select GT.
7. Failure to establish and maintain procedures defining and documenting design output in terms that allow adequate evaluation of conformance to design input requirements as required by 21 CFR 820.30(d). For example, acceptance criteria was not established for (i) the comparison of the Select GT to the Supreme II; (ii) the software validation of Version 104 used in both the Select GT and Supreme II meters; and (i)   for Supreme high control solution.
8. Failure to perform design validation under defined operating conditions on initial production units, lots, and batches, or their equivalents, as required by 21 CFR 820.30(g). For example, the meters used in the software validation of the Version 104 are not defined as production or demonstration units.
9. Failure to the design validation to ensure that devices conform to defined user needs and intended uses as required by 21 CFR 820.30(g). For example, the critical review meeting report dated December 23, 1997, indicates that the Select GT is marketable. That same meeting report includes concerns relating to software validation, the possible cracking of the on/off button and the recommended actions to address those issues.
10. Failure to establish and maintain procedures to control all documents that are required by 21 CFR 820.40 in that supporting details for changes to the Supreme  and the Supreme II high control

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solutions were not included with the respective Change Control Forms as required by your Documentation Change Control procedure A-000000-02.

Additionally, our records show that Chronimed has not submitted a 510(k) for a device called the Select GT. Your firm does not have marketing clearance from FDA; thus marketing the device is in violation of Sections 501(f)(1)(B) and 502(o) as follows:

The Select GT Blood Glucose Meter is adulterated under Section 501(f)(1)(B) in that it is a Class III device under Section 513(f) and does not have an approved application for premarket approval in effect pursuant to Section 515(a) or an approved application for an investigational device exemption under Section 520(g).

The Select GT Blood Glucose Meter is misbranded under Section 502(o) in that a notice or other information respecting the device was not provided to the FDA as required by Section 510(k).

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed of the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

The specific violations noted in this letter and in the form FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

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We have received your written response dated December 30, 1998, responding to the form FDA-483 that was issued to your firm on December 22, 1998. Your responses are noted and are being made part of the official file. Although your responses promise general correction to the concerns referenced in the form FDA-483, your response lacks specific documentation including procedures, forms, and reports that would allow us to assess the effectiveness of your proposed corrective actions.

Your responses to the specific items will be evaluated during our next scheduled inspection.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As CEO, the most responsible individual at Chronimed, Inc., it is ultimately your responsibility to ensure that devices manufactured at your facility in Eden Prairie, MN, are in compliance with each requirement of the Act and regulations.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time let us know why and when you expect to complete your corrections. Please direct your response to Compliance Officer Howard E. Manresa at the address indicated on the letterhead.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of Quality System Requirements for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at <http://www.fda.gov>.

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If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Manresa at (612) 334-4100 ext. 156.

Sincerely,

A handwritten signature in cursive script, appearing to read "Edwin S. Dee".

Edwin S. Dee
Acting Director
Minneapolis District

HEM/ccl

Enclosure: FDA-483, 12/22/98